REMARKS

In response to the Office Action mailed December 21, 2006, Applicants have amended claims 1 and 15. Claim 8 has been canceled. It is urged that support for all the above amendments may be found throughout the specification as originally filed, for example at page 32, lines 4-13 and page 96, lines 3-6. No new matter has been added. The above amendments are not to be construed as acquiescence with regard to the Examiner's rejections and are made without prejudice to prosecution of any subject matter removed or modified by this amendment in a related divisional, continuation or continuation-in-part application. Following the amendments, claims 1, 3, 4, 11 and 15 are pending in the application. Favorable reconsideration of the subject application is respectfully requested in view of the above amendments and the following remarks.

Specification

The Action objects to the disclosure because the first paragraph of the specification does not contain updated information regarding the status of parent applications.

Applicants have amended the first paragraph as required. Accordingly, the objection has been obviated.

Claim Rejections Under 35 U.S.C. § 101 (Utility) and 35 U.S.C. § 112, first paragraph (enablement)

Claims 1, 3, 4, 8, 11 and 15 stand rejected under 35 U.S.C. § 101 because the claimed invention allegedly lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility. The claims are also rejected under 35 U.S.C. § 112, first paragraph as allegedly lacking enablement since one of skill in the art would not know how to make and use the claimed invention due to its alleged lack of utility. In particular, the Action asserts at page 4 that the claimed sequence was obtained from a metastatic breast tumor library but that no further information about the sequence was provided. The Action goes on to assert that the presence of a polynucleotide in a tissue derived from cancer is not sufficient for establishing utility absent some information regarding a

correlative or causal relationship between the expression of the claimed cDNA and the disease. The Action additionally states that there must be some expression pattern that would allow the claimed polynucleotide to be used in a diagnostic manner.

Applicants respectfully traverse this rejection and submit that the claimed sequence of SEQ ID NO:52 was identified from a breast tumor cDNA library. However, contrary to the Action's assertion, mRNA expression analysis was performed for this sequence and is clearly described in the specification as filed at page 101, lines 10-29. In particular, the specification states that "...mRNA expression levels in breast tumor, normal breast and various other normal tissues were determined using microarray technology." Further, the specification states "The determined cDNA sequences of 131 clones determined to be over-expressed in breast tumor tissue compared to other tissues tested by a visual analysis of the microarray data are provided in SEQ ID NO:1-25 and 42-137." Applicants submit that the expression pattern of the claimed sequence of SEQ ID NO:52 clearly establishes a specific, substantial, and credible utility or, in the alternative, a well-established utility. In particular, and as noted by the Action, this expression pattern allows the claimed polynucleotide to be used, for example, in a variety of diagnostic settings for breast cancer.

Additionally, Applicants respectfully note that:

> As a matter of Patent Office practice, a specification which contains a disclosure of utility which corresponds in scope to the subject matter sought to be patented must be taken as sufficient to satisfy the utility requirement of § 101 for the entire claimed subject matter unless there is a reason for one skilled in the art to question the objective truth of the statement of utility..." *In re Langer*, 503 F.2d 1391, 183 USPQ 297 (CCPA 1974; emphasis in original).

Furthermore, Applicants submit that it is not required to provide evidence sufficient to establish that an asserted utility is true "beyond a reasonable doubt." *In re Irons*, 340 F.2d 974, 978, 144 USPQ 351, 354 (CCPA 1965; emphasis added); *See also* MPEP 2107.02. Moreover, an applicant need not provide evidence that establishes an asserted utility "as a matter of statistical certainty." Rather, a rigorous correlation is not necessary when a test is reasonably predictive of a result. *Nelson v. Bowler*, 626 F.2d 853, 856-57, 206 USPQ 881, 883-84 (CCPA

1980; emphasis added). Further still, in order to overcome the presumption of truth that an assertion of utility by the Applicant enjoys, Office personnel must establish that it is more likely than not that one of ordinary skill in the art would doubt (*i.e.*, "question") the truth of the statement of utility." (*e.g.*, MPEP 2107.02 IIIA; emphasis added). Applicants respectfully submit that this burden has not been met as no reasoned basis has been offered by the Examiner to establish that the skilled artisan would more likely than not question the position set forth by the Applicants.

When viewed in this light, Applicants submit that the claimed invention is adequately supported by a patentable diagnostic utility, and would be recognized as such by a skilled artisan in view of the instant disclosure. Reconsideration of the claims and withdrawal of the rejections are respectfully requested.

Claim Rejections Under 35 U.S.C. § 112, first paragraph (written description)

Claims 1, 3, 4, 8, 11 and 15 stand rejected under 35 U.S.C. § 112 because the claimed invention allegedly lacks written description. In particular, the Action asserts that the specification as filed does not adequately describe a representative number of fragment or variant sequences and that there is no description of common attributes or features of the members of the genus of sequences claimed.

Applicants note that claim 1 has been amended to remove recitation of % identity and degenerate variants of the polynucleotide of SEQ ID NO:52. Claim 15 has been amended to depend from claim 1. This amendment is made without prejudice or acquiescence and solely to advance prosecution. Applicants reserve the right to prosecute any subject matter removed or modified by this amendment in a related divisional, continuation or continuation-in-part application.

Applicants respectfully traverse the rejection and submit that the U.S.P.T.O. has specifically indicated that possession of an invention is more readily established, and correspondingly greater claim breadth is permissible, where an Applicant discloses functional and/or descriptive information concerning the specie(s) in an application, *e.g.*, a distinguishing identifying characteristic common among the members of a claimed genus (see *Guidelines for*

Examination of Patent Applications Under the 35 U.S.C. 112, para. 1, "Written Description" Requirement – Federal Register: January 5, 2001 (Volume 66, No. 4, pgs. 1099-1111). For example, at the bottom of pg. 1105, the *Guidelines* state that, "(a)n adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention." The Guidelines go on to state at page 1106, first column that "What is conventional or well known to one of ordinary skill in the art need not be disclosed in detail."

First, Applicants submit, as noted above, that the specification clearly discloses the breast-tumor expression pattern of the polynucleotide of SEQ ID NO:52. Second, Applicants submit that the specification clearly discloses the detailed structure of the polynucleotide set forth in SEQ ID NO:52. In view of the expression profile identified by Applicants for this sequence, the skilled artisan would undoubtedly understand and expect that a multitude of sequences related to SEQ ID NO:52, *e.g.*, fragments of the polynucleotide of SEQ ID NO:52 consisting of at least 20 contiguous nucleotides, or the complement thereof, would be diagnostically useful in the same capacity as the specific species of SEQ ID NO:52. More particularly, such fragments, based upon their structural similarity to, and thus specificity for, the sequence of SEQ ID NO:52, will hybridize, using assays known in the art and described in the specification, to the sequence of SEQ ID NO:52, and accordingly would be useful in detecting over-expression of SEQ ID NO:52 or the complement thereof, in a biological sample in the same manner as one would use the precise sequence of SEQ ID NO:52, or the complement thereof, to detect overexpression of SEQ ID NO:52 in a biological sample. This understanding and expectation on the part of the skilled artisan is soundly based upon fundamental scientific principles of nucleic acid hybridization.

Accordingly, Applicants disagree with the contention that they were only in possession of the specific sequence of SEQ ID NO:52 at the time this application was filed. Applicants submit that to accept such a position would result in the exclusion of an entire class of sequences related to SEQ ID NO:52 that are useful in the context of the Applicants' invention,

despite the fact that the skilled artisan would absolutely recognize the value of sequences related to SEQ ID NO:52 in the context of the Applicants' disclosure.

Moreover, by the present amendment, Applicants specifically incorporate the identifying characteristic into the claims under consideration, such that a fragment of the polynucleotide of SEQ ID NO:52 "detects the presence of the sequence provided in SEQ ID NO:52, or the complement thereof, in a biological sample". Accordingly, in view of the identifying characteristic disclosed for SEQ ID NO:52, Applicants respectfully submit that the skilled artisan would appreciate that Applicants were in clear possession of a genus of fragments of SEQ ID NO:52 that would be similarly useful in a diagnostic context based upon their specificity for the sequence of SEQ ID NO:52. Applicants thus submit that the instant claims fully comply with the written description requirements of 35 U.S.C. § 112, first paragraph. Reconsideration of the Examiner's rejection is respectfully requested.

Claim Rejections Under 35 U.S.C. § 102

Claim 1(b)-(d) stands rejected under 35 U.S.C. § 102(b) as allegedly anticipated by GenBank accession number AA193540. Claims 1, 3, 4, 8 and 11 stand rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Yang et al (WO 01/51638).

Without acquiescing to the rejection and without prejudice, Applicants have amended claim 1 to recite "an isolated polynucleotide consisting of the sequence provided in SEQ ID NO: 52, the complement thereof, or a fragment thereof wherein the fragment consists of at least 20 contiguous residues of the sequence provided in SEQ ID NO: 52, or the complement thereof, and wherein the fragment detects the presence of the sequence provided in SEQ ID NO:52, or the complement thereof, in a biological sample." Claim 15 has been amended to depend from claim 1. Applicants submit that none of the cited references teaches or suggests a sequence that consists of the exact sequence of SEQ ID NO:52 or a fragment thereof that consists of at least 20 contiguous nucleotide. As such, Applicants submit that the claimed invention is not anticipated by the cited references. Reconsideration of the claims and withdrawal of the rejection are respectfully requested.

Claim Rejections Under 35 U.S.C. § 103

Claim 15 stands rejected under 35 U.S.C. § 103 as allegedly unpatentable over Yang et al. (WO 01/51638) and the Stratagene Catalog (page 39, 1988). In particular, the Action asserts that Yang *et al.* teach oligonucleotides which hybridize to SEQ ID NO:35 (the complement of which is 100% identical, over nucleotides 314-692, to SEQ ID NO:52) but do not teach kits. The Action relies on the Stratagene Catalog to make up this deficiency.

Without acquiescing to the rejection and without prejudice, Applicants have amended claim 15 to depend from claim 1 which has been amended to recite "an isolated polynucleotide consisting of the sequence provided in SEQ ID NO: 52, the complement thereof, or a fragment thereof wherein the fragment consists of at least 20 contiguous residues of the sequence provided in SEQ ID NO: 52, or the complement thereof, and wherein the fragment detects the presence of the sequence provided in SEQ ID NO:52, or the complement thereof, in a biological sample." Applicants submit that the cited references, taken for what they teach individually or as a whole, do not teach or suggest the claimed invention. In particular, as noted above, Yang *et al.* does not teach or suggest a sequence that consists of the sequence of SEQ ID NO:52 or a fragment thereof that consists of at least 20 contiguous nucleotides. Page 39 of the Stratagene Catalog does not overcome this deficiency and, in fact, teaches no sequences at all. As such, Applicants submit that the claimed invention is not obvious in view of the cited references. Reconsideration of the claims and withdrawal of the rejection are respectfully requested.

Rejections under nonstatutory obviousness-type double patenting

Claims 1, 3, 4 and 11 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 1, 3, 4, 22 and 23 in copending Application No. 10/010,742.

Applicants submit that the rejection has been obviated by the above amendments. Nonetheless, as term of the present patent will not be affected, if the PTO determines that a terminal disclaimer is necessary to overcome this rejection and the claims are otherwise allowable, Applicants will consider submitting an executed terminal disclaimer.

In view of the above amendments and remarks, the claims are now believed to be in condition for allowance. A good faith effort has been made to place the application in condition for allowance. However, should any further issue require attention prior to allowance, the Examiner is requested to contact the undersigned at 206-622-4900 to resolve same.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Respectfully submitted,

SEED Intellectual Property Law Group PLLC

/Julie A. Urvater/
Julie A. Urvater, Ph.D., Patent Agent
Registration No. 50,461

JAU:ms

701 Fifth Avenue, Suite 5400
Seattle, Washington 98104
Phone: (206) 622-4900
Fax: (206) 682-6031

889560_1.DOC